

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

|  |   |                       |
|--|---|-----------------------|
| <b>THE CLEVELAND CLINIC FOUNDATION, et</b> | ) |                       |
| <b>al.,</b>                                | ) |                       |
|  | ) | Civil Action No.      |
| Plaintiffs,                                | ) | 1:17-cv-00198-LMB-IDD |
|  | ) |                       |
| v.   | ) |                       |
|  | ) |                       |
| <b>TRUE HEALTH DIAGNOSTICS LLC,</b>        | ) |                       |
|  | ) |                       |
|  | ) |                       |
| Defendant.                                 | ) |                       |

**MEMORANDUM IN SUPPORT OF PLAINTIFFS’  
MOTION FOR LEAVE TO AMEND COMPLAINT**

Plaintiffs The Cleveland Clinic Foundation (“CCF”) and Cleveland HeartLab, Inc. (“CHL”) (collectively, “Plaintiffs”), move this Court for leave to file their Second Amended Complaint (“SAC”) (attached hereto as Exhibit 1),<sup>1</sup> to add allegations that Defendant True Health Diagnostics LLC (“True Health”) infringes a third patent belonging to CCF that the United States Patent and Trademark Office (“USPTO”) issued just a few days ago on April 4, 2017. Plaintiffs’ new allegations involve the same infringing conduct and significantly overlap the allegations in the First Amended Complaint (“FAC”) as well as the subject matter of the two patents currently in suit.

The Federal Rules of Civil Procedures allow a party to amend its pleading as a matter of right within 21 days; otherwise, pleadings may be amended with the written consent of the opposing party or by order of Court. Fed. R. Civ. P. 15(a). On April 6, 2017, counsel for the

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<sup>1</sup> Attached as Exhibit 2 is a comparison of the FAC with the SAC showing deleted text in red and strikethrough and inserted text in blue and double underscored. To avoid burdening the Court, Plaintiffs did not include the exhibits to the SAC because they are voluminous and largely duplicative of the exhibits attached to the FAC. Upon the Court’s granting this motion, Plaintiffs will file the SAC and its exhibits with the Court.

parties conferred to determine if True Health would consent to this amendment given the substantial overlap in the allegations and given that this case is in its infancy. On April 6-9, 2017, counsel continued to confer by email. Even though Plaintiffs moved quickly and in good faith to amend the FAC once the new patent issued, and even though True Health will not be prejudiced in any way by this amendment, True Health has refused to consent to the amendment. Accordingly, Plaintiffs respectfully request that this Court grant their motion for leave to file the SAC.

## **I. BACKGROUND**

CCF is a nationally-recognized top medical center in the United States and in the world. (FAC, ¶ 6.) It is particularly well known for its advances in the treatment of cardiovascular disease (“CVD”). (*Id.*) Indeed, CCF operates the No. 1-ranked heart program in the United States, and its cardiovascular practice is the largest in the United States. (*Id.*) In 2009, CCF helped organize a group of local and national investors and physicians to launch CHL for the purpose of advancing MPO testing. (*Id.*, ¶ 19.) Today, CHL is a premier inflammation testing laboratory with the most experience in the field. (*Id.*, ¶ 7.)

CVD is the number-one killer of both men and women in the United States. (*Id.*, ¶ 14.) Physicians rely on laboratory tests to diagnose disease, guide treatment, and manage patient health risks; in particular, they use blood tests to diagnose CVD. (*Id.*, ¶ 15.) While cholesterol testing is most commonly used to identify CVD risk, approximately 50 percent of heart attack victims previously displayed normal cholesterol levels. (*Id.*, ¶ 16.) Thus, there has been a glaring need for a test that is minimally invasive for the patient, easy to administer (like a cholesterol test), but that provides data better predictive of CVD risk. (*Id.*)

Responding to this long-felt need in the medical profession, researchers at CCF developed a new approach for determining CVD risk that analyzes inflammation of the blood

vessels by detecting the presence of a biomarker called myeloperoxidase (“MPO”) in the blood stream. (*Id.*, ¶ 17.) Inflammation is a symptom of CVD rather than a potential cause, and CCF determined that MPO is highly predictive of the risk of CVD. (*Id.*) The CCF inventors discovered a new and highly innovative method for “seeing” MPO in the bloodstream, using analytical techniques that had never been used to detect MPO free flowing in blood for the purpose of predicting CVD. The inventors discovered that when MPO is detected in this manner, the resulting MPO value can be meaningfully compared to statistically-derived control values to predict the risk of CVD. (*Id.* ¶ 18.) CCF’s innovative methods and techniques provide a reliable method for identifying patients at risk of developing CVD. (*Id.*) In order to protect its investment in this discovery, CCF filed several patent applications relating to MPO testing. (*Id.*, ¶ 19.)

Since its inception, CHL has worked to create and expand the market for MPO testing services and products, to ensure proper use and quality of MPO testing, and to continue MPO-related innovation. (*Id.*, ¶ 20.) CHL commercializes the MPO inventions by performing MPO tests directly for physicians and hospitals as well as offering MPO testing reagents and services to other laboratories so that they can perform the same high-quality testing directly for physicians and hospitals. (*Id.*, ¶ 21.)

On February 21, 2017, the USPTO issued United States Patent 9,575,065 (“the ’065 Patent”). (*Id.*, ¶ 30.) Plaintiffs filed this lawsuit that same day, alleging that True Health infringes the ’065 Patent by performing MPO testing in accordance with the patented methods. (*Id.*, ¶¶ 43-58.) On February 28, 2017, the USPTO issued United States Patent 9,581,597 (“the ’597 Patent”). That same day, Plaintiffs filed the FAC alleging that True Health infringes the ’597 Patent by performing MPO testing in accordance with the methods claimed in the ’597

patent. (*Id.*) Because True Health had not yet answered the original complaint, Plaintiffs amended the original complaint as of right. Fed. R. Civ. P. 15(a).

On March 6, 2017, counsel for True Health contacted counsel for Plaintiffs and requested a 90-day extension to answer or otherwise respond to the complaint. (Exhibit 3.) Counsel for Plaintiffs responded that while Plaintiffs would likely be willing to agree to a modest extension of 7 to 14 days, Plaintiffs could not understand why True Health would need a 90-day extension, which is roughly equivalent to the entire discovery period in this Court. (*Id.*) Counsel for Plaintiffs also asked True Health whether it intended to answer the complaint or to file a motion. (*Id.*) Counsel for True Health declined to answer this question, but proposed a compromise of a 21-day extension. (*Id.*) As a matter of courtesy and to avoid unnecessary motion practice, Plaintiffs did not oppose True Health's requested extension. (*Id.*) True Health filed its unopposed request for an extension to answer on March 10, 2017, which the Court granted on March 13, 2017. (Dkt. Nos. 17-18.)

On April 4, 2017, the USPTO issued United States Patent 9,612,242 ("the '242 Patent"). The '242 Patent claims a method including a first test to detect the presence of MPO plus a second test to determine the levels of a second biomarker called F2-isoprostane, which is an oxidation product generated when MPO is present in the blood.

On April 5, 2017, True Health filed a motion to dismiss this case on the grounds that the patents-in-suit claim patent-ineligible subject matter under 35 U.S.C. § 101. (Dkt. No. 19.)

On April 6, 2017, counsel for the parties conferred in person about the '242 Patent and Plaintiffs' intention to amend the complaint to add the new patent to this case. Counsel for Plaintiffs provided a copy of the '242 Patent, and requested that True Health consent to Plaintiffs' amending the complaint. In exchange, Plaintiffs indicated that they would agree to a

reasonable extension of the deadline for True Health to answer the SAC if True Health needed some additional time to investigate the allegations with respect to the '242 Patent. Counsel for True Health agreed to consider the issue and respond promptly with its position.

Later that same day, counsel for Plaintiffs wrote a confirming email, providing another copy of the '242 Patent as well as the proposed SAC. (Exhibit 4.) In that email, counsel for Plaintiffs reiterated that Plaintiffs intended to file their motion to amend on Friday, April 7, 2017, if an agreement could not be reached. (*Id.*)

On the morning of April 7, 2017, counsel for True Health responded that True Health “may be willing to agree provided that sufficient additional time is built into any scheduling order to allow us to investigate and address the new claims and to answer or otherwise respond.” (*Id.*) Counsel for Plaintiffs promptly wrote back and requested a call to discuss the details as soon as True Health’s counsel was able to do so. (*Id.*) After two more email exchanges, counsel for True Health declined to have a call, citing “other commitments.” (*Id.*)

On Sunday, April 9, 2017, True Health’s counsel sent an email rejecting any proposal to file an unopposed motion, asserting that True Health would be prejudiced unless “the parties and the Court also agree to push back all discovery dates and the trial date to account for the new allegations regarding the '242 patent[.]” (*Id.*) True Health indicated that it would further consider and discuss the proposal, but only if “you or your local counsel is aware of a way to guarantee that additional time is built into the scheduling order.” (*Id.*) True Health refused to consent “unless we get a guarantee that the Court will modify the entire schedule and trial date as if the case first begins upon the filing of the newly amended complaint.” (*Id.*)

This morning, Plaintiffs’ counsel responded to True Health’s position, noting that True Health’s proposal is contrary to this Court’s procedures. (*Id.*) This Court has not yet issued its

scheduling order, and when it does issue the order, the deadlines will be the same whether there are two or three patents in the case. (*Id.*) The parties cannot stipulate to a longer discovery period or different pretrial conference date than what this Court would normally enter. And, True Health's suggestion that Plaintiffs should have to bring a separate suit to add the newly-issued '242 patent is unreasonable and highly inefficient. For these reasons, Plaintiffs' counsel explained that it appeared the parties were at an impasse, and Plaintiffs would proceed to file their opposed motion to amend.

Thus, notwithstanding that this Court has not yet issued a scheduling order in this case and discovery has not yet begun, True Health has not consented to Plaintiffs' amendment of its infringement allegations to include the '242 Patent, requiring Plaintiffs to bring this opposed motion and unnecessarily burden the Court.

## **II. AMENDMENTS TO PLEADINGS SHOULD BE FREELY GIVEN**

When leave to amend the pleadings is sought, district courts "should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). Both the Supreme Court and the Fourth Circuit have emphasized that the rules encourage liberal pleading amendments. *Foman v. Davis*, 371 U.S. 178 (1962); *Ward Elecs. Serv. Inc. v. First Commercial Bank*, 819 F.2d 496 (4th Cir. 1987). In *Foman*, the Supreme Court explained:

In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought [to amend the pleadings] should, as the rules require, be "freely given."

371 U.S. at 182. Applying the *Foman* rule, the Fourth Circuit encourages district courts to permit liberal amendments to the pleadings. *Ward*, 819 F.2d at 497 (explaining that *Foman* "mandates a liberal reading of the rule's direction for 'free' allowance"); *see also Hockerson-Halbertstadt, Inc. v. JSP Footwear, Inc.*, 104 F. App'x 721 (Fed. Cir. 2004) (affirming decision

granting leave to amend complaint when defendant “would suffer only nominal prejudice, if any” from the amendment).

While *Foman* discusses a number of factors that a court may consider—undue delay, bad faith, dilatory motives, repeated failures to cure deficiencies, undue prejudice, and futility—in this Circuit, “[t]he law is well settled ‘that leave to amend a pleading should be denied *only when* the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would be futile.’” *Edwards v. City of Goldsboro*, 178 F.3d 231, 242 (4th Cir. 1999) (emphasis in original).

### III. THE COURT SHOULD GRANT PLAINTIFFS’ MOTION

Plaintiffs’ motion should be granted. This case is similar to, and much more compelling than, the circumstances in *Swimways Corp. v. Bravo Sports*, Case No. 2:08-cv-481, Dkt. No. 253 (E.D. Va. Sept. 8, 2009) (Jackson, J.) (attached as Exhibit 5). There, the lawsuit was filed October 7, 2008, the same day that USPTO issued the patent-in-suit. After the case had been pending for a nearly a year, the USPTO issued a new patent from a continuation application stemming from the patent-in-suit. The Plaintiff sought leave to amend the complaint to add the newly issued patent. The amended complaint asserted “additional claims for the same accused products already at issue in this case.” The Court concluded “that Defendants will not be unduly prejudiced or burdened by allowing the amendments.” (*Id.* at 2.) The Court further found that “allowing the amended complaints is in the interest of judicial economy and efficient resolution of this case.” (*Id.*)

Plaintiffs’ motion in this case is much more compelling than the motion in *Swimways*. Here, like there, the new claims are directed at the same accused activity already at issue in the case, but here, unlike *Swimways*, the case has been pending for only a few weeks and virtually nothing has happened yet. On April 5, 2017, True Health filed a motion to dismiss the case,

claiming that the patents-in-suit claim patent-ineligible subject matter, and this Court has not yet issued a scheduling order. Any slight adjustments to accommodate addition of the '242 Patent can be easily addressed in the parties' discovery plan once the Court issues a scheduling order, and True Health will not be unduly prejudiced or burdened in any way. As in *Swimways*, allowing Plaintiffs' to file the SAC is in the interest of judicial economy and efficient resolution of the case.

Moreover, none of the remaining considerations from *Foman* is applicable here. Plaintiffs have not unduly delayed in seeking to amend the complaint. The USPTO issued the '242 Patent on April 4, 2017, just a few days ago. Plaintiffs have acted promptly to assert their claims that True Health infringes the '242 Patent. Plaintiffs have not acted in bad faith, nor are they motivated by any dilatory motives. To the contrary, Plaintiffs are eager to move this case forward. Further, there is nothing deficient in Plaintiffs' prior pleadings, and these new allegations to add the related claims that True Health infringes the '242 Patent are also sufficiently pled. And, finally, Plaintiffs' SAC would not be futile. Plaintiffs seek to amend their claims because True Health is conducting both MPO and F2-isoprotane testing in violation of Plaintiffs' patent rights. This amendment is important to ensure that True Health's infringing conduct is stopped and that Plaintiffs are fully compensated for True Health's infringement of their patent rights.

Because Plaintiffs' amendment will not prejudice True Health, the motion was not brought in bad faith, and the amendment would not be futile, Plaintiffs' motion should be granted. *Edwards*, 178 F.3d at 242 (explaining that leave to amend may be denied only upon a showing of prejudice, bad faith or futility).



#### IV. CONCLUSION

For all these reasons, Plaintiffs respectfully request that this Court grant their motion for leave to file the SAC, and order True Health to answer, move or otherwise plead in response by no later than fourteen (14) days after entry of the SAC. Further, if the court grants the motion, Plaintiffs' request that the Court deny True Health's motion to dismiss as moot as it will be superseded by the amended complaint, but without prejudice to True Health's renewing motion when it answers the SAC.

Dated: April 10, 2017

Respectfully submitted,

/s/ Tara Lynn R. Zurawski

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*Counsel for Plaintiffs*

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Cleveland HeartLab, Inc.*

**CERTIFICATE OF SERVICE**

I certify that on April 10, 2017, a copy of the foregoing was filed electronically with the Clerk of Court using the ECF system. A copy of this filing will be served on Defendant by operation of the Court's ECF system.

Dated: April 10, 2017

*/s/ Tara Lynn R. Zurawski*

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